## IAP20 Rec'd PCT/PTO 31 MAY 2006

29248/29

PTO/SB/08A (07-05) Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Substitute for form 1449/PTO

INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number

PCT/BF2004/000172

Filing Date

I.A. Decamber 2, 2904

Art Unit

Examiner Name

Sheet

Attorney Docket Number

			U. S. PATEN	T DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Document Number  Number-Kind Code <sup>2 (f known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	<sup>US-</sup> 5,364,857 A	11-15-1994	Bode Greuel	
	2	<sup>US-</sup> 5,762,960 A	06-09-1998	Dodman	
	3	US- 5,780,474 A	07-14-1998	Peglion, et al.	
	4	<sup>US-</sup> 2005/0119253 A1	06-02-2005	Buntinx	
	5	<sup>US-</sup> 2005/0119248 A1	06-02-2005	Buntinx	
	6	<sup>US-</sup> 2005/0119249 A1	06-02-2005	Buntinx	
	7	<sup>US-</sup> 2005/0203130 A1	09-15-2005	Buntinx	
		US-			
-		US-			
		US-			

		FORE	IGN PATENT DOC	JMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code <sup>3</sup> "Number <sup>4</sup> "Kind Code <sup>5</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T <sup>6</sup>
000000000000000000000000000000000000000			06.17.1992		000000000000000000000000000000000000000	
	9	WO 98/11897 A	03-26-1998	Eli Lilly and Company		
	10	WO 98/43646 A	10-08-1998	Akzo Novel N.V.		
	11	WO 00/64441 A	11-02-2000	Respiratorius AB		
<u> </u>	12	WO 01/98298 A	12-27-2001	H. Lundbeck A/S		
	13	WO 02/051833 A	07-04-2002	H. Lundbeck A/S		

			<del></del>
Examiner	Carab Dibanald	Date	25/1/2000
Signature	i /Saran Pinonak/	Considered	1 N5/1/2/2009
Olg/lata/o		Considered	00/17/2000

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

AP20 Rec d PCT/PTO 31 MAY 2006

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

	ute for form 1449/PTC		or 1995, no persons ar	Complete if Known			
Cuban	ato 101 101111 144301 FC	•		Application Nu		U.S. National Phase of PCT Application No. PCT/BE2004/000172 & F A A A A A	
INF	ORMATIO	N DIS	CLOSURE	Filing Date	I.A.	December 22004 300 70 5	
STATEMENT BY APPLICANT				First Named In	ventor	Erik Buntinx	
	(Uso se many s	choote se no	cossani	Art Unit	_		
(Use as many sheets as necessary)				Examiner Name			
Sheet	2	-5	5	Attorney Docket	Number	20248/20	

<del></del>	1	NON PATENT LITERATURE DOCUMENTS
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issu number(s), publisher, city and/or country where published.
000000000000000000000000000000000000000		SCHINDLER T., et al., "Palliative medical management in anxiety and depression." Zeischrift Fur
	1	Allgemeinmedizin, vol. 74, No. 21, November 5, 1998, pp. 973-978.
	<del>+5</del>	VOLMAT R., et al., "The treatment of depressions by Cledial. Evolution and clinical state and handwriting."  Psychologic Medicale, vol. 16 (16), 1888, pp. 1645-1622.
		FOUKS, et al., "Treatment of character disorders with a new butyrophenone: R. 3345 or pipamperone."
000000000000000000000000000000000000000	16	Annales Medico-Psychologiques, vol. 124, No. 5, 1966, pp. 677-681.
	17	SQUELART P, et al., "Pipamperone (Dipiperon), a useful sedative neuroleptic drug in troublesome chronic pyschotic patients." Acta Psychiatrica Belgica, vol. 77, No. 2, March 1977, pp. 284-293.
	18	KOCH HJ, et al., "Successful therapy of tardive dyskinesia in a 71-year-old woman with a combination of tetrabenazine, olanzapinr and tiapride." International Journal of Clinical Practice, vol. 57, No 2, March 2003, pp. 147-149.
	19	DIEBOLD K, et al., "Are psychoactive-drug-induced changes in plasma lipid and lipoprotein levels of significance for clinical remission in psychiatric disorders?" Pharmacopsychiatry, 1998, Vol 31, pp.60-67.
	20	GROZINGER M, et al., "Melperone is an inhibitor of the CYP2D6 catalyzed O-demethylation of venlafaxine." Pharmacopsychiatry, vol. 36, No. 1, January 2003, pp. 3-6.
	21	PERUGI G, et al., "Effectiveness of adjunctive gabapentin in resistant bipolar disorder: Is it due to anxious-alcohol abuse comorbidity?" Journal of Clinical Psychopharmacology, vol. 22, No. 6, 2002, pp. 584-591.
	22	WIELING, W et al., "Initial orthostatic hypotension as a cause of recurrent syncope: A case report." Clinical Autonomic Research, vol. 11 (4), 2001, pp. 269-270.
	23	DATABASE PHARMAPROJECTS ONLINE! PJB Publications Ltd., December 1999. Caesar Accession No. 1498 (2 pages).

Examiner	/Sarah Pihonak/	Date	05/14/2009
Signature	, & saisain i in to i cost o	Considered	05/14/2009

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

## IAPZO Rec'd PCT/PTO 31 MAY 2006

PTO/SB/08B (07-05) Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute	e for form 1449/PTO				Complete if Known	
Cossulati				Application Number	U.S. National Phase of PCT Application No. PCT/BE2004/000172	
			CLOSURE	Filing Date I.A.	December 20000 702	
STATEMENT BY APPLICANT				First Named Inventor	Erik Buntinx	
	(Use as many she	ets as n	ecessary)	Art Unit	÷	
	, coo co many and	30 11		Examiner Name		
Sheet	3	of	5	Attorney Docket Number	29248/29	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
Eng. abs.	24	ADLER L, et al., "Praxis Der Stationaeren Akutbenhandlung Von Manien Restrospektive Vergleichsuntersuchung An Je 100 Patienten Zweier Psychiatrischer Zentren. Practice of In-Patient Acute Treatment of Manias." Fortschritte Der Neurologie Psychiatrie, Stuttgart, vol. 62, No.12, 1994, pp. 479-488.	
•	25	ANSOMS C, et al., "Sleep disorders in patents with severe mental depression: double-blind placebo-controlled evaluation of the value of pipamerone (Dipiperone)." Acta Psychiatrica Scandinavica, vol. 55, No. 2, February 1977, pp. 116-122.	
	26	LEYSEN JE, et al., "Receptor interactions of new antipsychotics: relation to pharmacodynamic and clinical effects." International Journal of Psychiatry in Clinical Practice, vol. 2, No. 1, 1998, pp. S3-S17.	
	27	VANHOENACKER P, et al., "Efficient expression of the human dopamine D4.2 receptor: Positive influence of pipamperone on expression levels." Abstracts of the Society for Neuroscience, vol. 26 No.1/2, 2000.	
	28	SCHOTTE A, et al., "Risperidone compared with new and reference antipsychotic drugs: In vitro and in vivo receptor binding." Psychopharmacology, vol. 124, No. 1-2, 1996, pp. 57-73.	
000000000000000000000000000000000000000	<u>2</u> 9	WOCCONB, "Phermaksisgische depressionbehandlung, Phermassisgisch treatment of depression."  Therapeutische Umschau, vol. 57, No. 2, 2000, pp. 81-89.	000000000000000000000000000000000000000
-	30	VAN DE VIJVER DAMC, et al., "Antipsychotic and Parkinson's disease: Association with disease and drug choice during the first 5 years of antiparkinsonian drug treatment." Eur. J. Clin. Pharmacology, vol. 58, 2002, pp. 157-161.	
Eng. abs.	31	JOVIC NI, et al., "Phenomenology and treatment of delirium in Alzheimer's disease" Revue Medicale De La Suisse Romande, vol. 117, No. 9, September 1997, pp. 655-658.	
	32	ENGELBORGHS S, et al., "Amino acids of biogenic amines in cerbrospinal fluid of patients with Parkinson's disease." Neurochemical Research, vol. 28 No. 8, August 2003, pp. 1145-1150.	
	33	NEWMAN-TANCREDI A, et al., "[35S]-guansosine-5'-O-(3-thio) triphosphate binding as a measure of efficacy at human recombinant dopamine D4.4 receptors: Actions of antiparkinsonian and antipsychotic agents."  Journal of Pharmacology and Experimental Therapeutics, vol. 282 (1), 1997, pp. 181-191.	

Examiner	/Sarah Pihonak/	Date	05/14/2009
Signature		Considered	00/14/2009

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:



Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitut	e for form 1449/PTO				Complete if Known
Qubstitut				Application Number	U.S. National Phase of PCT Application No. PCT/BF2004/000172
INF	DRMATION	I DIS	CLOSURE	Filing Date I.A.	December 2:2004 / 580 962
STATEMENT BY APPLICANT			PPLICANT	First Named Inventor	Erik Buntinx
	//			Art Unit	
	(Use as many she	ets as n	ecessary)	Examiner Name	
Sheet	4	of	5	Attorney Docket Number	29248/29

Examiner	Cite	NON PATENT LITERATURE DOCUMENTS  Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	ĺ
Initials*	No.1	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	34	TARZI FI, et al., "Role of dopamine D4 receptors in neuropsychiatric disorders." Journal of Neurochemistry, vol. 81, supp. 1, June 2002, p. 33, Abstract.	
-	35	TARZI FI, et al., "Dopamine D4 receptors: Significance for molecular psychiatry at the millennium." Molecular Psychiatry, vol. 4, No 6, November 1999, pp. 529-538.	
	36	LEOPOLD NA, "Risperidone treatment of drug-related psychosis in patients with parkinsonism." Movement Disorders, vol. 15, No 2, March 2000, pp. 301-304.	
	37	TAHAR AH, et al., "Antidyskinetic effect of JL-18, a clozapine analog, in parkinsonian monkeys." European Journal of Pharmacology, vol. 399, No 2-3, July 7, 2000, pp. 183-186.	
	38	ZESIEWICZ TA, et al., "Clozapine withdrawal symptoms in a Parkinson's disease patient." Movement Disorders, vol. 17, No 6, November 2002, pp. 1365-1367.	
Eng. abs.	39	FALTRACO F, et al., "Akuelle therapeimoglichkeiten der alzheimer demenz (current therapeutical strategies in dementia)." Neurol. Rehabil. 2003, 9(1), pp. 15-22.	
Eng. abs.	40	ETCHEPAREBORDA MC, "Neurocognitive and pharmacological approach to specific learning disorders."  Database Medline Online, US National Library of Medicine, February 1999, and Revista De Neurologia, vol. 28, suppl. 2, February 1999, pp. S81-S93, Abstract.	
	41	STAHL SM, et al., "Examination of nightime sleep-related problems during double-blind, placebo-controlled trials of galantamine in patients with Alzheimer's disease." Current Medical Research and Opinion 2004, vol. 20, No 4, pp. 517-524.	
	42	MENESES, A, "Are 5-HT 1B/1D and 5-HT 2A/2B/2C receptors involved in learning and memory processes?" Drugs 1999, vol. 2 (8), 1999, pp. 796-801.	
	43	WIRZ-JUSTICE A, et al., "Haloperidol disrupts, clozapine reinstates the circadian rest-activity cycle in a patient with early-onset Alzheimer disease." Alzheimer Disease and Associated Disorders, vol. 14, No 4, 2000, pp. 212-215.	

Examiner	/Sarah Pihonak/	Date Considered	05/14/2009
Signature		Considered	03/14/2009

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

## AP20 Rec'd PCT/PTO 31 MAY 2006

PTO/SB/08B (07-05)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO				Complete if Known		
Cabsilian	010110111111111111111111111111111111111			Application Number	U.S. National Phase of PCT Application No. PCT/BE2004/009172	
			CLOSURE	Filing Date I.A.	December 2, 2664 90 90 2	
STATEMENT BY APPLICANT				First Named Inventor	Erik Buntinx	
(Use as many sheets as necessary)				Art Unit		
				Examiner Name		
Sheet	5	of	5	Attorney Docket Number	29248/29	

	NON PATENT LITERATURE DOCUMENTS	
Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
44	FAHS H, et al., "Thymoregulateurs Dans L'Agitation et les Troubles Du Comportement Chez le Sujet Dement a Propos de Huit Cas, Anticonvulsivants and Aggresive Behaviors in Alzheimer's Disease. Eight Cases Reports." L'Encephale, vol. 25, No 2, 1999, pp. 169-174.	
45	WERTH E, et al., "Decline in long-term circadian rest-activity cycle organization in a patient with dementia." Journal of Geriatric Psychiatry and Neurology, vol. 15, No 1, April 2002, pp. 55-59.	
46	MELTZER HY, et al., "Plasma clozapine levels and the treatment of L-Dopa-induced psychosis in Parkinson's disease. A high potency effect of clozapine." Neuropsychopharmacology, vol. 12, No 1, 1995, pp. 39-45.	
47	MUNCHAU A, et al., "Pharmacological treatment of Parkinson's disease." Postgraduate Medical Journal, vol. 76, October 2000, pp. 602-610.	
	44 45 46	Cite No. 1 Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.  FAHS H, et al., "Thymoregulateurs Dans L'Agitation et les Troubles Du Comportement Chez le Sujet Dement a Propos de Huit Cas, Anticonvulsivants and Aggresive Behaviors in Alzheimer's Disease. Eight Cases Reports." L'Encephale, vol. 25, No 2, 1999, pp. 169-174.  WERTH E, et al., "Decline in long-term circadian rest-activity cycle organization in a patient with dementia."  Journal of Geriatric Psychiatry and Neurology, vol. 15, No 1, April 2002, pp. 55-59.  MELTZER HY, et al., "Plasma clozapine levels and the treatment of L-Dopa-induced psychosis in Parkinson's disease. A high potency effect of clozapine." Neuropsychopharmacology, vol. 12, No 1, 1995, pp. 39-45.  MUNCHAU A, et al., "Pharmacological treatment of Parkinson's disease." Postgraduate Medical Journal, vol.

Examiner Signature	/Sarah Pihonak/	Date Considered	05/14/2009

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.